DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 25, 2014

Masimo Corporation
Marguerite Thomlinson
Senior Director, Regulatory Affairs
40 Parker
Irvine, California 92618

Re: K142394
Trade/Device Name: Masimo Root Monitoring System And Accesories
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, JKS, CCK, BZQ, DQA, DPZ, GXY, GWQ, OLT, OLW, OMC, ORT
Dated: August 25, 2014
Received: August 27, 2014

Dear Marguerite Thomlinson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4. Indications for Use Statement

Indications for Use

510(k) Number: _____

Device Name: Masimo Root Monitoring System

Indications for Use:

The Masimo Root Monitoring System is indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments.

The Masimo Root Monitoring System can transmit data for supplemental remote viewing and alarming (e.g., at a central station).

The optional Masimo Radical-7 Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radical-7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Radical-7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical-7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

The optional Masimo Radius-7 Wearable Pulse Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and/or respiratory rate (RRa). The Masimo Radius-7

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 801 Subpart D)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 4. Indications for Use Statement

Wearable Pulse Oximeter and accessories are indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+), intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

ISA CO2: CO_2

ISA AX+: CO_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: CO_2, O_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

The optional SEDLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 40 Parker Irvine, CA 92618 Phone: (949) 297-76 FAX: (949) 297-7592
Date:	August 25, 2014
Contact:	Marguerite Thomlinson Senior Director, Regulatory Affairs
Trade Name:	Masimo Root Monitoring System and Accessories
Common Name:	Patient Monitor
Classification Regulation/ Product Code:	21 CFR 878.2300, Class II/MWI 21 CFR 862.3220, Class II/JKS 21 CFR 868.1400, Class II/CCK 21 CFR 868.2375, Class II/BZQ 21 CFR 870.2700, Class II/DQA 21 CFR 870.2710, Class II/DPZ 21 CFR 882.1320, Class II/GXY 21 CFR 882.1400, Class II/GWQ 21 CFR 882.1400, Class II/OLT 21 CFR 882.1400, Class II/OLW 21 CFR 882.1400, Class II/OMC 21 CFR 882.1400, Class II/ORT
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Device modification and new indications for use
Predicate Devices:	K140188 – Masimo Root Monitoring System
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

Section 5. 510(k) Summary

Device Description – Disease/Conditions that Device Diagnose, Treat, Prevent, Cure or Mitigate, Including Patient Population

The Root Monitoring System (Root) is a multifunctional device that monitors vital signs of patients from neonates to adults. Parameters monitored by Root include non-invasive functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), respiratory rate (RRa), inspired/expired gases during anesthesia, recovery and respiratory care, state of the brain by real-time data acquisition and processing of EEG signals, and Patient State Index (PSI) which is an EEG variable that is related to the effect of anesthetic agents.

Explanation of Why Differences in Indication Statement Are Not Critical to Intended Use, and Why Difference Do Not Affect Safety and Effectiveness of Device When Used as Labeled

Root is intended to be used with the previously FDA cleared measurement technologies for the modules of:

- Masimo Radical-7 Pulse CO-Oximeter (Radical-7 module), with cleared technologies of SpO2, pulse rate, SpCO, SpMet, SpHb and RRa monitoring per K110028.
- Masimo Radius-7 Pulse Oximeter (Radius-7 module), with cleared technologies of SpO2, pulse rate and RRa monitoring per K110028.
- ISA-Infrared Sidestream Gas Analyzer (ISA module), with cleared technologies of breathing gases and respiratory rate monitoring per K103604.
- Sedline Sedation Monitor with Frontal PSI and SEDTrace EEG Electrode Set (Sedline module), with cleared technologies of EEG and PSI monitoring per K051874.

Root is intended to be used as an alternative user interface to facilitate access control and monitoring device functions and to connect system networks such as the Patient SafetyNet (K071047).

Device Description – General Description from Labeling, Including Explanation of How Device Functions, Scientific Concepts that Form Basis For the Device

Root displays patient monitoring information from the connected modules. Visual alarms are shown on the Root display and audible alarms are generated through the Root internal speaker. When the module is disconnected from Root, the monitoring information from the module is no longer displayed on Root.

Section 5. 510(k) Summary

Data from connected modules, including patient monitoring data, can be communicated to network systems. Root also functions as a pass-through means for communicating information between connected devices and network systems.

The predicate device, Masimo Root Monitoring System (Root) was cleared in K140188, is the same as the subject device, Masimo Root Monitoring System (Root). The main difference is that the subject device includes the addition of the optionally connected Masimo Radius-7 Pulse Oximeter (Radius-7) module.

Device Description – Significant Physical and Performance Characteristics of the Device

The significant physical characteristics for Root include an LCD touchscreen for patient monitoring. The instrument can be powered by AC or by its internal rechargeable battery. The approximate size and weight of the instrument are 11” x 10.5” x 5.5” (27.9 cm x 26.7 cm x 14 cm) and approximately 8 pounds.

The device specifications are shown below for the general functions of the subject device, Root.

FEATURE	**SPECIFICATION**
Display	Color LCD touchscreen
Connected Module	**Parameter**
Radical-7	Parameters per K110028
Radius-7	Parameters per K110028 for SpO2, pulse rate and RRa
ISA Module	Parameters per K103604
Sedline Module	Parameters per K051874
General	
Visual/audible alarm	IEC60601-1-8 compliant
Storage/recording	Trend/data storage
Electrical	
AC Power	100-240 volt, 47-63 Hz
Battery	Rechargeable battery
Interface	
Root and Device/Module Connection	Wired/docking interface Wireless interface MOC-9 interface Iris interface Nurse call interface USB interface SD card interface
Network Connectivity	Ethernet Wi-Fi, 802.11 a/b/g; Bluetooth 2.0
Mechanical	
Dimensions	11 x 10.5 x 5.5 inch (27.9 x 26.7 x 14 cm)
Weight	Approximately 8 lbs (3.63 kg)

Section 5. 510(k) Summary

FEATURE	SPECIFICATION
Environmental	
Operating Temperature Storage Temperature Humidity	32 to 122°F (0-50°C) -40 to 158°F (-40 to 70°C), 10-95% non-condensing humidity
Mode of Operation	
Mode of Operation	Continuous

Intended Use

Root serves as a convenient alternative user interface to integrate modules to provide health care professionals the ability to access, control and monitor measurement technologies (within the respective modules) that have been previously cleared by the FDA. Root does not affect the intended use, or alter the indications for use, for the cleared modules with which it is intended to function. Additionally Root is intended to communicate with network systems.

Indications For Use

The Masimo Root Monitoring System is indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments.

The Masimo Root Monitoring System can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station).

The optional Masimo Radical-7 Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radical-7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Radical-7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical-7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

The optional Masimo Radius-7 Wearable Pulse Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and/or respiratory rate (RRa). The Masimo Radius-7 Wearable Pulse Oximeter and accessories are indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities environments.

Section 5. 510(k) Summary

The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+), intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

ISA CO2: CO_2

ISA AX+: CO_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: CO_2, O_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

The optional SEDLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

Technological Characteristics

Principle of Operation

Root functions as an alternative user interface that allows access, control and monitoring from the connected modules.

Data from connected modules, including patient monitoring data, can be communicated to network systems. Root also functions as a pass-through means for communicating information between connected devices and network systems.

Mechanism of Action for Achieving the Intended Effect

The system begins functioning when the power is turned on for Root.

Root communicates with connected modules and displays the modules' patient monitoring information on the Root display. The healthcare provider controls the functions of each module using the Root touchscreen display. Visual alarms are shown on the Root display and audible alarms are generated through the Root internal speaker.

By connecting modules or devices to Root, data can be communicated between Root and network systems via wired or wireless connection. Information from network systems can be shown on the Root display for viewing and notification purposes.

Section 5. 510(k) Summary

Once use is complete, the user then turns the power “off” for Root.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

Similarities and Differences between Predicate Device, Root (K140188) and Subject Device, Root

The main features which are the same for predicate and subject devices are listed below.

- Both have the same fit, form and function.
- Both can function with the Radical-7, ISA and/or Sedline modules.
- Both have the same principle of operation and the mechanism of action for achieving the intended effect.
- Both can communicate with a network system such as the Patient SafetyNet (K071047) through wired or wireless connection.

The main difference between the predicate and the subject devices is that the Radius-7 is an added measurement module that can function with the subject device. Below is a summary of the monitored parameters and their substantial equivalence.

			TABLE 18			
Monitored Parameter	**Test Description**	**Test Objective**	**Study Endpoints**	**Results Summary**	**Conclusion**	**Substantial Equivalence (SE) Yes/No?**
SpO2, PR, and RRa	Display verification of Root and Radius-7 module	To verify Root user interface when connected to Radius-7	Test personnel began and ended test cases for the Root with Radius-7 user interface, and recorded the test results per test procedures.	Pass	Root correctly displayed monitoring information from Radius-7.	Yes SE to K140188
SpO2, PR, PI, PVI and RRa	Display validation of Radius-7 module	To validate human factors/ usability	Clinicians (users) started and completed the usability test cases and recorded the test results per test procedures.	Pass	Radius-7’s ease of use was validated by the clinicians.	Yes SE to K140188
SpO2, PR, and RRa	Display validation of Radius-7 module	To validate human factors/ usability for Root and Radius-7	Clinicians (users) started and completed the usability test cases and recorded the test results per test procedures.	Pass	Radius-7’s ease of use was validated by the clinicians.	Yes SE to K140188

Section 5. 510(k) Summary

			TABLE 18			
Monitored Parameter	**Test Description**	**Test Objective**	**Study Endpoints**	**Results Summary**	**Conclusion**	**Substantial Equivalence (SE) Yes/No?**
N/A. General battery functions.	Battery life and operation verification for Radius-7 module	To verify battery life and operation for Radius-7	Test personnel began and ended battery life/operation test cases, and recorded the test results per test procedures.	Pass	Radius-7's battery life and operation was verified to work properly.	Yes SE to K140188
N/A. General display and speaker functions.	Visual/audio alarm verification for Radius-7 module	To verify visual/audio alarm compliance to IEC 60601-1-8	Test personnel began and ended visual/audio alarm test cases per the IEC standards, and recorded test results.	Pass	Radius-7 visual/audio alarms are compliant to IEC60601-1-8.	Yes SE to K140188
SpO2, PR, and RRa	Visual/audio alarm verification for Root and Radius-7	To verify audio and visual alarms on Root	Test personnel began and ended audio/visual alarm verification test cases, and recorded test results per test procedures	Pass	Root correctly generated visual/audio alarms from Radius-7.	Yes SE to K140188
N/A. General wireless connection	Wireless (Bluetooth) connection verification for Root and Radius-7	To verify Bluetooth connection between Root and Radius-7	Test personnel began and ended Bluetooth verification test cases, and recorded test results per test procedures.	Pass	Root properly connected to Radius-7 via Bluetooth connection.	Yes SE to K140188
N/A. General wireless connection	Wireless connection verification for Root and Radius-7	To verify wireless co-existence per FDA Wireless Guidance	Test personnel began and ended wireless co-existence testing per FDA Guidance, and recorded the test results.	Pass	Root with Radius-7 met FDA Wireless Guidance requirements for wireless co-existence testing.	Yes SE to K140188
N/A. General wireless connection	Wireless connection verification for Root and Radius-7	To verify wireless quality of service per FDA Wireless Guidance	Test personnel began and ended wireless quality of service testing verification per FDA Guidance, and recorded test results.	Pass	Root with Radius-7 met FDA Wireless Guidance requirements for wireless quality of service testing.	Yes SE to K140188
SpO_2, PR, SpCO, SpMet, SpHb and RRa	Display verification of Root and Radical-7 module	To verify Eagle (Root) user interface	Test personnel began and ended test cases for the Root user interface, and recorded the test results per test procedures.	Pass	Root correctly displayed monitoring information from the connected modules.	Yes SE. See predicates in K140188.
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Display validation of Root and Radical-7, ISA and Sedline modules	To validate human factors/ usability	Clinicians (users) started and completed the usability test cases and recorded the test results per test procedures.	Pass	Root's ease of use was validated by the clinicians.	Yes SE. See predicates in K140188.

Section 5. 510(k) Summary

			TABLE 18			
Monitored Parameter	**Test Description**	**Test Objective**	**Study Endpoints**	**Results Summary**	**Conclusion**	**Substantial Equivalence (SE) Yes/No?**
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Display validation of Root and Radical-7, ISA and Sedline modules	To validate human factors/ usability	Clinicians (users) started and completed the usability test cases and recorded the test results per test procedures.	Pass	Root's ease of use was validated by the clinicians.	Yes SE. See predicates in K140188.
EEG and PSI	Display verification of Root and Sedline module	To verify Sedline indicator and display	Test personnel began and ended test cases for indictor/display verification, and recorded the test results per test procedures	Pass	Root correctly displayed monitoring information from the Sedline module.	Yes SE. See predicates in K140188.
Breathing Gases and RR	Display verification of Root and ISA module	To verify ISA module indicator and display	Test personnel began and ended test cases for indictor/display verification, and recorded the test results per test procedures	Pass	Root correctly displayed monitoring information from the ISA module.	Yes SE. See predicates in K140188.
N/A. General wireless functions	Wireless interface verification of information from any connected module	To verify the wireless communication between a module fixture and Root	Test personnel began and ended test cases for the wireless interface verification, and recorded the test results per test procedures	Pass	A module fixture wirelessly connected to Root in the similar communication as a wired connection.	Yes SE. See predicates in K140188.
N/A. General docking functions	Docking station function verification for Root and Radical-7	To verify battery management	Test personnel began and ended battery management test cases, and recorded the test results per test procedures.	Pass	Root docking station interfaced correctly with the Radical-7 module.	Yes SE. See predicates in K140188.
EEG and PSI	MOC-9 interface verification for Root and Sedline module	To verify MOC-9 Port EEPROM	Test personnel began and ended MOC-9 EEPROM verification test cases, and recorded the test results per test procedures	Pass	The MOC-9 interface functioned correctly in EEPROM identification.	Yes SE. See predicates in K140188.
Breathing gases, RR, EEG and PSI	MOC-9 interface verification for Root and ISA and Sedline modules	To verify EEPROM Identification for Iris and MOC-9	Test personnel began and ended EEPROM Identification test cases for Iris and MOC-9, and recorded test results per test procedures.	Pass	The MOC-9 and Iris interfaces functioned correctly in EEPROM identification for connected modules.	Yes SE. See predicates in K140188.

Section 5. 510(k) Summary

			TABLE 18			
Monitored Parameter	**Test Description**	**Test Objective**	**Study Endpoints**	**Results Summary**	**Conclusion**	**Substantial Equivalence (SE) Yes/No?**
Breathing Gases and RR	Root and ISA module verification	To verify Root/PhaseIn (ISA) capnography module integration	Test personnel began and ended ISA integration test cases, and recorded the test results per test procedures.	Pass	Root correctly displayed monitoring information from the ISA module.	Yes SE. See predicates in K140188.
EEG and PSI	Root and Sedline module verification	To verify Root/Sedline integration	Test personnel began and ended Sedline integration test cases, and recorded the test results per test procedures	Pass	Root correctly displayed monitoring information from the Sedline module.	Yes SE. See predicates in K140188.
EEG and PSI	Root and Sedline module verification	To verify Sedline board communication	Test personnel began and ended Sedline board communication test cases, and recorded test results per test procedures	Pass	Root correctly communicated with the Sedline module.	Yes SE. See predicates in K140188.
N/A. General display and speaker functions	Visual/audio alarm verification for Root	To verify visual/audio alarm compliance to IEC 60601-1-8	Test personnel began and ended visual/audio alarm test cases per the IEC standards, and recorded test results.	Pass	Root visual/audio alarms are compliant to IEC60601-1-8.	Yes SE. See predicates in K140188.
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Visual/audio alarm verification for Root and Radical-7, ISA and Sedline modules	To verify visual/audio alarm acknowledgment	Test personnel began and ended visual/audio alarm acknowledgment test cases, and recorded the test results per test procedures.	Pass	Root correctly generated visual/audio alarms from the connected modules.	Yes SE. See predicates in K140188.
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Visual/audio alarm verification for Root and Radical-7, ISA and Sedline modules	To verify audio and visual alarms	Test personnel began and ended audio/visual alarm verification test cases, and recorded test results per test procedures	Pass	Root correctly generated visual/audio alarms from the connected modules.	Yes SE. See predicates in K140188.
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Alarm limit controls verification for Root and Radical-7, ISA and Sedline modules	To verify alarm limit controls	Test personnel began and ended alarm limit controls verification test cases, and recorded test results per test procedures	Pass	Root correctly generated alarm limits from the connected modules.	Yes SE. See predicates in K140188.

Section 5. 510(k) Summary

			TABLE 18			
Monitored Parameter	**Test Description**	**Test Objective**	**Study Endpoints**	**Results Summary**	**Conclusion**	**Substantial Equivalence (SE) Yes/No?**
N/A. General wired connection	Wired connection verification for Root	To verify Ethernet connection	Test personnel began and ended Ethernet verification test cases, and recorded test results per test procedures	Pass	Root functioned correctly in its connectivity via the Ethernet.	Yes SE. See predicates in K140188.
N/A. General wired connection	Wired connection verification for Root	To verify Iris connectivity to network system	Test personnel began and ended Iris/Patient SafetyNet connectivity test cases, and recorded test results per test procedures	Pass	Root's Iris interface functioned correctly in its connectivity to system networks such as the Patient SafetyNet.	Yes SE. See predicates in K140188.
N/A. General wireless connection	Wireless connection verification for Root	To verify internal radio module	Test personnel began and ended radio module verification test cases, and recorded test results per test procedures.	Pass	Root's internal radio module performed correctly.	Yes SE. See predicates in K140188.
N/A. General wireless connection	Wireless connection verification for Root	To verify wireless co-existence per FDA Wireless Guidance	Test personnel began and ended wireless co-existence testing per FDA Guidance, and recorded the test results.	Pass	Root met FDA Wireless Guidance requirements for wireless co-existence testing.	Yes SE. See predicates in K140188.
N/A. General wireless connection	Wireless connection verification for Root	To verify wireless quality of service per FDA Wireless Guidance	Test personnel began and ended wireless quality of service testing verification per FDA Guidance, and recorded test results.	Pass	Root met FDA Wireless Guidance requirements for wireless quality of service testing.	Yes SE. See predicates in K140188.

Non-clinical Testing

See below for the non-clinical testing that was completed.

- Electrical safety testing per IEC60601-1
- EMC testing per IEC60601-1-2
- Alarm testing per IEC60601-1-8
- Biocompatibility testing per ISO-10993
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Wireless testing per FDA Wireless Guidance
- Software verification per FDA Software Guidance
- Mechanical and environmental testing

- Cleaning validation

The results demonstrate that all requirements and performance specifications were satisfied, and that the subject device is substantially equivalent to the predicate device.

Clinical Testing

No clinical testing was done.

Conclusion

It is concluded that the subject device, Masimo Root Monitoring System, is substantially equivalent to its predicates with respect to safety and effectiveness, based on the nonclinical tests discussed above.